SPECIFICATION AMENDMENTS

Page 1, last paragraph, continuing onto page 2:

Meniscal tears are a common problem in the United States, especially among amateur and professional athletes. While menisci are also located in the shoulder, the most common meniscus injury occurs in the knee. There are two menisci in each knee. Each year, tens of thousands of people suffer meniscal tears, particularly in or at the site of one or both knees. If these tears are not repaired, there may be a progressive deterioration of the cartilage, leading to the painful rubbing and wearing of bones which had previously been covered by cartilage. This, in turn, leads to inflammatory synovitis, arthritis and other debilitating ailments. Consequently, there are at least 30,000 to 40,000 meniscal excisions or repairs to the shoulder and the knee performed each year.

Page 5, second full paragraph:

It is ~~still yet~~ another object of the present invention to provide a suture passer having means for positioning of the suture.

Page 5, third full paragraph:

It is ~~still yet~~ another object of the present invention to provide a parallel needle guide to allow for an easier and more

successful placement of a second needle in close proximity to the first needle that has been previously inserted in the area of a tissue tear.

Page 6, first paragraph:

~~And another~~ Another object of the present invention is to provide a surgical cannula having a sharp distal tip which is adapted to pierce tissue while at least one strand of suture extends out of the cannula~~'s~~ sharp distal tip, wherein the sharp distal tip of the cannula is specially configured ~~so as~~ to minimize the possibility of damaging or severing the suture during the tissue piercing operation.

Page 7, first full paragraph:

In one embodiment of the invention, the hollow cannula is connected to the upper surface of the handle and the hollow cannula terminates at a rearward opening between the first and second guide means.

_____ In another embodiment of the invention, the hollow cannula is received within a bore formed in the handle, with the bore terminating at an opening in the upper surface of the handle between the first and second guide means.

Page 16, tenth paragraph:

FIG. 27A, FIG. 27B, and ~~FIG.~~ FIGS. 28-31 are cross-sectional top views at various stages of an operation where the posterior region of the meniscus is being repaired.

Page 19, last paragraph, continuing onto page 20:

Figures 1-7 illustrate the meniscal suture passer 1, used for the passage of a suture in a confined area of the body during surgery. The suture passer 1 comprises a longitudinally extending hollow cannula 2 having a central passage slidingly receiveable of a surgical suture, and a manually graspable handle 3 connected to the hollow cannula 2 for manipulation thereof. A first guide means is connected to the upper surface of the handle 3 for releasably, guidingly holding the surgical suture. A second guide means for guidingly holding the suture, is also connected to the upper surface of the handle 3. The second guide means is proximal to the first guide means. The suture passer 1 in ~~figures~~ Figures 1-6 comprises ~~a~~ the cannula 2, ~~a~~ the handle 3, a rearward opening 4 near the distal end of the handle 3, a distal loop 5, and a proximal loop 6. The distal loop 5 serves as the first guide means, and the proximal loop 6 serves as the second guide means. Distal loop 5 preferably comprises a single turn open wire loop having a first axis of rotation of the loop and proximal loop 6 is preferably a 1 ½ pigtail open wire loop having a second axis of rotation of the loop. The loops 5, 6 are preferably parallel to one another. In one embodiment, the wire loops 5 and 6 are preferably perpendicular to the handle 3 with the first axis of rotation and the second axis of rotation

transverse to said longitudinally extending hollow cannula 2. In another embodiment, the axes of rotation of loops 5 and 6 are parallel to the longitudinally extending cannula 3. Near the distal end of the handle there is ~~an~~ the opening 4 which leads from the handle 3 to the cannula 2. The handle ~~is~~ preferably is provided with gripping means and ~~is~~ preferably is knurled at 7, so that the surgeon has a better grip on the suture passer 1.

Page 20, last paragraph, continuing onto page 21:

The cannula 2 may be attached and enter through an opening at the concentric center ~~8~~ of the handle 3 as shown in Figure 1. The hollow cannula 2 is received within a bore 8 formed in the handle 3 with the bore 8 terminating at ~~an~~ the opening 4 in ~~the~~ an upper surface 9 of the handle 3 intermediate the first and second guide means. In an alternative embodiment, the cannula may be connected to the upper surface 9 of the handle 3, as shown in Figure 3. In this embodiment of the invention, there is no opening into or through the handle 3. Instead, the hollow cannula 2 terminates at a rearward opening 10 between the first and second guide means directly on top of the handle 3. Additionally, in the embodiment of figure 1, the handle of the suture passer is rounded, whereas in the embodiment of Figures 3 and 4, the suture passer handle is flattened on the side upon which the ~~proximal end 10 of the~~ cannula 2 resides. Additionally, in the embodiment of Figure 3, the distal loop 5 resides on the cannula 2 just prior to the proximal opening ~~4~~ 10 of the cannula 2.

Page 21, the first full paragraph:

The central passage of the cannula should have a diameter large enough to allow sliding passage of two surgical sutures therethrough. ~~The~~ A distal opening 11 of the cannula should also have a diameter large enough to allow engagement with the tip of the spinal or epidural needle for the purpose of passage of the suture between the cannula and the needle.

Page 21, the last full paragraph:

In the embodiment of ~~figure~~ Figure 1, the cannula 2 from its distal opening 11 to the point at which it enters the handle ranges in length from about 6.0 cm to abouve 20.0 cm, and ~~more preferable~~ preferably is about 12.0 cm in length. The opening of the cannula 2 is preferably from about .08 cm to about .32 cm in width, and ~~more preferable~~ preferably is about .16 cm in width. The wall of the cannula 2 is preferably from about .01 cm to about .05 cm in thickness, and more preferably is about .0254 cm in thickness. The handle preferably has a width ranging from about 0.64 cm to about 1.28 cm, and more preferably is about 0.96 cm in width.

Page 21, last paragraph, continuing onto page 22:

The wire of the wire loops as shown in Fig. 5 ranges from about 0.10 to about 0.14 cm in diameter "a" and ~~is~~ preferably is attached to the handle by a mounting structure 12 about 0.1 to about 0.4 cm in height "h".

Page 22, first full paragraph:

In the embodiment of the invention illustrated in Figure 6, the suture passer 1 is similar to the invention illustrated in Figure 3; however, the cannula 2 is flush with the flattened surface of the handle 1 bearing the wire loops 5 and 6. A segmented piece 13 upon which the distal loop 5 resides attaches the cannula 2 to the handle 3. The proximal opening 10 of the cannula opens ~~on~~ near the proximal side of the segmented piece 13.

Page 24, second full paragraph:

~~The~~ A cannula bender 30 shown in Figures 12 and 13 is designed to bend a cannula to a desired curvature. It is different from the existing tube or cannula benders in that it allows the cannula be bent to various radii of curvature. The cannula bender 30 can also bend the cannula in more than one plane.

Page 24, fourth full paragraph:

There are symmetrical ~~curbed~~ curved bolsters having steps 33, 34, 35, and 36 on top of the base. The stepped configuration provides the higher steps 34, 35 with a smaller radius of curvature. The steps range from about .6 cm to about 4 cm in height, with a preferred height of about 1 cm. (Two steps are illustrated but more can be provided).

Page 25, first full paragraph:

The cannula can be bent again in a different plane by rotating the cannula while maintaining the cannula bender in the same orientation. The pre-bent cannula can be contoured against the bolster in a second ~~planes~~ plane as long as the curvature is less than the height of the step of the bolster.

Page 26, last paragraph, continuing onto page 27:

Additionally, there is at least one stylet typified by stylet 29 shown in Figure 11 in the surgical repair kit for each needle included in the repair kit. The stylet is kept ~~in~~ on the needle until the needle is passed through the meniscus. This ~~presents~~ prevents the needle(s) from being clogged with tissue and cartilage as it is pushed through the cartilage. A needle clogged with tissue will, of course, not allow the suture to be passed through the needle to the suture passer.

Page 27, last paragraph, continuing onto page 28:

The surgical repair kit which includes the suture passer, at least two surgical needles of predetermined length, and at least one stylet for each needle, may also contain an optional third needle of greater length than the other two needles, the parallel needle guide, and a template. If the cannula is made of metal, a cannula bender may be included in the repair kit. While the repair kit may be used for any surgery, the repair kit is extremely useful in meniscal repair ~~kit~~.

Page 28, first full paragraph:

In repairing the middle third of the meniscus, ~~the~~ an arthroscope 37 should enter through the ipsilateral portal 38 as shown in Figure 14. The suture passer 1 should enter through the contralateral portal 39. The epidural needle is loaded through the hole on one end of the needle guide using a one handed technique to avoid accidental puncture of the surgeon's opposite hand.

Page 28, fourth full paragraph:

The second method of determining where to insert the needles is to view the meniscal tear and to keep the synovial meniscal junction in view~~. Palpate~~ while palpating along the joint line with a tip of a finger or a meniscal probe. The area of maximal wall motion at the synovial meniscal junction indicates the point at which the epidural needle should be inserted.

Page 29, first full paragraph:

The needles may be advanced with a twisting motion if difficulty is encountered in penetrating the tough meniscal tissue. As shown in Figure 15, ~~the~~ an inner rim 40 of ~~the~~ a meniscal tear 41 may be buttressed with the tip of the cannula 2 of the suture passer to stabilize it against the advancing needle 18.

Page 29, second full paragraph:

Using the parallel needle guide, two epidural needles are inserted through the guide and across the meniscal tear with ~~the~~ a long epidural needle 42 being inserted through the needle guide at a desired separation distance from the shorter needle (as shown in Figure 16). This longer needle is inserted through the meniscal tissue, preferably behind the shorter needle. The stylets are removed from the needles. A suture is passed through the "first" needle. The tip of the cannula of the suture passer is introduced into the joint cavity through a small incision. The distal opening of the cannula is placed at or near the opening of the needle through which the suture has been passed. There are areas in the joint cavity, although visible through the arthroscope which are not accessible with a straight cannula. Consequently, prior to the introduction of the suture passer, the cannula of the suture passer may be bent on the cannula bender. The ~~curbed~~ curved cannula allows the surgeon to reach remote areas where the meniscus is being repaired.

Page 29, last paragraph, continuing onto page 30:

In a preferred method for passing the suture from the cannula to the needle, the needle, preferably an epidural needle with a Huber tip, engages the opening of the cannula (Figure 17). The more posterior needle is advanced into the joint and the surgeon captures the tip of the needle with the tip of the cannula. For ease of passage, it is preferable that the cannula and needle meet at about a ~~15°-20°~~ 15° - 20° angle. The opening of the needle should be facing away from the apex of engagement

between the cannula and the needle. The suture is passed directly from the cannula into the tip of the needle or vice versa.

Page 30, first full paragraph:

By careful manipulation, ~~the~~ a suture 43 is fed through the needle and into the cannula. With the tip of the cannula and the needle securely engaged, the suture is fed (Figure 18) into the hub of the needle until it exits the proximal end of the cannula at the handle of the suture passer. It is advisable to pull the suture three quarters of the way through. The suture is then looped onto the distal guide and is threaded back into the cannula. The suture is then engaged onto the proximal guide (Figure 19).

Page 30, last paragraph, continuing onto page 31:

The first needle is removed, and with the two limbs of the suture held separately by the proximal and distal loops, one limb of the suture is advanced by sliding the suture with the index finger over the top surface of the handle so that the suture emerges from the tip of the cannula (Figure 20). The suture, via the suture passer, is now fully controllable with one hand. The tip of the second needle and the tip of the cannula are brought into close proximity and the suture is passed from the loaded suture passer into the opening of the second needle and through the second needle. The suture is advanced until it exits from the hub of the second needle (Figure 21). The second needle is

partially removed so that the tip of the second needle is buried within ~~the~~ soft tissue 44 (Figure 22). The suture is disengaged from the guides on the handle of the suture passer.

Page 31, first full paragraph:

While grabbing both ends of the suture, the suture is pulled through the cannula into ~~the~~ a joint 45 (Figure 23). With the second needle still in place, a stab incision is made along the shaft of the second needle down to the level of ~~the~~ a joint capsule 47 but not beyond (Figure 24). The second needle is removed and the soft tissue is dissected all the way down to the joint capsule by spreading the soft tissue with a pair of small forceps 48 (Figure 25). The other limb of the suture is then retrieved through this "stab incision" with a meniscal probe 49 (Figure 26) and the sutures are tied after all of the sutures have been put into place.

Page 35, last paragraph, continuing onto page 36:

Tab portion 210 extends centrally and proximally from proximal edge 212 of the fin's main portion 208 (see Fig. 40). Tab portion 210 is located in the same plane as main portion 208 (see Fig. 41) and is preferably generally rectangular in shape, although other tab shapes may also be used without departure from the present invention. Tab portion 210 includes an upper tab projection 218 (see Fig. 40) which projects upwardly out of the tab portion's upper edge 220, and a lower tab projection 222 which projects downwardly out of the tab portion's lower edge

224. Upper tab projection 218 defines an upper, distally facing tab shoulder 226, and lower tab projection 222 defines ~~an~~ a lower, distally facing tab shoulder 230. Tab projections 218 and 222 are located between the proximal edge 212 of the fin's main portion 208 and the proximal edge 232 of the tab portion 210 (see Fig. 40). Tab shoulders 226 and 230 are aligned with one another.

Page 41, last paragraph, continuing onto page 42:

To release a cannula 200 from handle 300, the proximal end 378 (see Figs. 36 and 37) of release rod 364 is forced distally so as to move the release rod against the biasing force of spring 376. As release rod 364 moves distally through handle bore 348, the release rod's deflection surface 382 (see Fig. 37A) will engage the proximal ~~end~~ edge 232 (see Fig. 40) of the cannula's tab portion 210 and deflect the tab portion 210 laterally so as to disengage the cannula's distally facing tab shoulders 226 and 230 (see Fig. 40) from the housing's proximally facing sidewall shoulders 342 and 344 (see Figs. 36 and 38). As release rod 364 continues to move distally through handle bore 348, the release rod's drive surface 384 (see Fig. 37A) will engage the cannula's proximal ~~surface~~ edge 232 (see Fig. 40), whereby the entire cannula will be driven distally so that the cannula's two tab projections 218 and 222 will clear the housing's two sidewall projections 338 and 340 (see Figs. 38, 39 and 39A). This will unlock the cannula from the handle. Cannula 200 may thereafter be manually withdrawn from the handle by pulling the cannula in a distal direction.

Page 42, first full paragraph:

Thus, it will be seen that a variety of different cannulas 200 can be releasably attached to the handle 300. These cannulas can be ~~a~~ blunt or sharply pointed, and they may be straight or curved, as required for a particular surgical procedure.

Page 44, last paragraph, continuing onto page 45:

FIGS. 53-55 illustrate how a simple stitch can be established across two pieces of tissue using the present invention. More particularly, a length of suture 400 is first loaded onto suture passer 100 by feeding one end 400A of the suture into the suture passer's cannula 200. Suture end 400A is left sitting within the length of cannula 200. Suture length 400B is loaded onto the suture passer's proximal suture guide 304. The intermediate portion of suture 400 will extend along the handle's distal upper surface 310. Then the distal end of the suture passer's cannula 200 is forced through two pieces of tissue 500A and 500B until the distal end of the cannula exits the tissue. Next, the surgeon urges suture 400 distally through the cannula until suture end 400A exits the tip of the cannula (see Fig. 53). Then the suture passer is withdrawn from tissue 500A and 500B, paying out the suture as it goes, so that suture 400 extends through both pieces of tissue (see Fig. 54). Next, suture 400 is withdrawn from the suture passer and suture ends 400A and 400B are tied off into a knot (see Fig. 55).

Page 45, last paragraph:

FIGS. 56-58 illustrate how a suture loop can be passed across two pieces of tissue using the present invention. More particularly, a length of suture 400 is first loaded onto suture passer 100 by feeding one end 400A of the suture into the suture passer's cannula 200. Suture end 400A extended all the way out the distal end of the cannula (see Fig. 56). Suture end 400A is then brought back to the suture passer's handle, so that the length of the suture will engage the blunted needle heel 274 as it exits from the cannula (see Fig. 57). Alternatively, suture end 400A could be left dangling until the force of tissue penetration brings suture end 400A back against the blunted needle heel 274. Suture length 400B is loaded onto the suture passer's proximal suture guide 304. The intermediate portion of suture 400 will extend along the handle's distal upper surface 310. Then the distal end of the suture passer's cannula 200 is forced through two pieces of tissue 500A and 500B until the distal end of the cannula exits the tissue. As this occurs, the suture will be carried through the tissue so that a loop of suture will reside on the far side of the tissue (see Fig. 58). Then the suture passer is withdrawn from tissue 500A and 500B, paying out the suture as it goes, so that both suture ends 400A and 400B will reside on the near side of the tissue, with a loop of suture remaining on the far side of the tissue.

Page 46, last paragraph:

FIGS. 62-64 illustrate how a simple stitch can be converted to a mattress stitch with a suture loop using the present invention. More particularly, a loop of suture 402 is first positioned on the far side of the tissue using the technique of FIGS. 56-58, and a single strand of suture 404 is passed through the tissue using the technique of Figs. 53 and 54 (see Fig. 62). Then the end of suture 404 is drawn through the loop of suture 402 (see Fig. 63). Finally, the loop of suture 402 is withdrawn back through tissue 500A, 500B, carrying the strand of suture 404 with it (see Fig. 64).